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While the U.S., to the best of our knowledge, remains free of both Bovine Spongiform Encephalopathy (BSE), otherwise known as "Mad Cow Disease," as well as its human counterpart, variant Creutzfeldt-Jacob Disease (vCJD), the experiences of European countries that grew complacent and now are suffering from epidemics of BSE and, in some cases, vCJD should make us more vigilant than we are at present. The agent that causes BSE has often found a way to pierce small chinks in the public health armor. For this reason, it is critical not only to maintain our defenses but also to strengthen them in the several areas I will highlight in this testimony.

I will address four areas: 1. How the agent that causes BSE might enter the country; 2. How the agent, if it entered the country or arose spontaneously within the country, could spread; 3. Whether the U.S. is doing enough testing to detect the disease; and 4. Whether there are medical practices that might spread the disease.

How could the BSE agent enter the country?

We have serious concerns about the ability of customs inspectors to adequately police the borders. With the dramatic increase in global trade, the workload of these inspectors is only likely to grow. Transhipments between countries can make determining the origin of meat and bone meal quite difficult. This is, of course, an issue that extends well beyond BSE to encompass broader issues of food safety.

An issue of particular concern is that of dietary supplements. In 1994, the government, unwisely, essentially deregulated the dietary supplement industry. Whereas, prior to the Dietary Supplement, Health and Education Act (DSHEA), the industry had the burden of demonstrating the safety of its products, now the Food and Drug Administration (FDA) must demonstrate that a particular dietary supplement is unsafe before it can take action. Moreover, this now-$14 billion industry is not required to prove the efficacy of its products and the FDA has still failed to issue Good Manufacturing Practice (GMP) regulations for dietary supplements four years after the agency commenced rulemaking on this issue and seven years after DSHEA. Manufacturers are not required to register with the FDA and the agency only inspects approximately 1% of imported items subject to its jurisdiction, a fraction that may be still lower for dietary supplements. The agency has issued an Import Alert for materials sourced from BSE countries, but compliance is voluntary.

For BSE, this means that an unscrupulous manufacturer could literally take a British cow brain, crush it,

dry it out, formulate it into a dietary supplement and export it to the U.S. Indeed, a letter by Dr. Scott Norton in the New England Journal of Medicine mentions a product available in the U.S. with 17 cow organs including brain, pituitary, and pineal gland. Due to DSHEA, the FDA is limited in what it can do. Instead of claiming that its regulatory authority over dietary supplements is adequate, as it often does publicly, the agency should be coming back to the Congress to undo the damage done by DSHEA. The best option would be to simply repeal DSHEA. In the alternative, we recommend a variety of improvements, including a mandatory adverse event reporting requirement for all dietary supplement manufacturers, mandatory risk warnings, requirements for company and product registration, and identification of the raw ingredients and the source (by country) for each of the ingredients in each product. This is, of course, a problem that goes well beyond the risk of vCJD; over 100 people have been killed by ephedra, and the agency seems essentially powerless to act. Releasing the GMP regulations for dietary supplements is necessary, but will not suffice to adequately protect American consumers from vCJD that might be caused by these products.

If the BSE agent entered the country, how might it spread?

A. Feeding practices

Since 1997, the FDA has had a ban on the feeding of mammalian parts to ruminants (e.g., cows, goats, sheep), the main route by which the BSE epidemic occurred in Britain and would be amplified in the U.S. This ban requires that manufacturers take action to prevent the commingling of two types of feed: those intended for ruminants, and those intended for non-ruminants (e.g., pigs, fish, chickens which can be fed material from mammals).

FDA inspections to date provide evidence that this commingling is possible. The March 2001 FDA inspection report findings (http://www.fda.gov/cvm/index/updates/bsemar3.htm), while improved from the January 2001 findings, still shows that 14% of renderers and 13% of FDA-licensed feed mills do not have adequate procedures to prevent mammalian parts from entering ruminant feed: i.e., cows could still be recycled and fed to other cows. (This is precisely what happened in the Purina Mills plant in Texas in which, purely through the voluntary admission of the company, the FDA learned that cow parts had entered cow feed. One thousand, two hundred and twenty-two cows had to be removed from the food chain.) Moreover, 23% of renderers and 63% of FDA-licensed feed mills have still not been inspected for compliance with the feed restrictions and some 6,000 to 8,000 feed mills are not even required to register with the FDA. Of the 1,829 non-FDA licensed feed mills that handle material prohibited from use in ruminant feed, 18% do not have adequate procedures to prevent the recycling of mammalian parts as feed for ruminants. If the industry does not come into better compliance with the mammal-to-ruminant ban, the FDA should consider whether a mammal-to-mammal ban is justified.

In addition, the FDA feed ban contains an exemption that should be ended. Despite U.S. Department of Agriculture (USDA) objections, the FDA permits the feeding of so-called plate waste (leftover food that has been prepared and/or served to humans) in feed for ruminants. The European Union, Canada and Mexico have banned such practices and so should we.

Finally, there is the issue of Chronic Wasting Disease (CWD), a Transmissible Spongiform Encephalopathy (TSE) of wild and captive elk and deer. While there exists no evidence that humans have become infected from eating deer or elk, current USDA procedures permit deer and elk from a herd with a proven case of CWD to enter the food chain. The problem is that deer and elk are exempt from the USDA's Meat Inspection Act, under which the packer has the burden of demonstrating the safety of his or her product. Instead, deer and elk would have to be restricted under the FDA's Food, Drug and Cosmetic Act, which places the burden upon the agency to demonstrate potential harm and provides no funds to compensate farmers if their herd is seized. This creates an incentive for farmers not to be forthcoming about CWD in their herds. This could be addressed either by a specific regulation excluding CWD-affected herds from the food chain and providing for compensation for the rancher or by bringing deer and elk under the Meat Inspection Act, which does provide for compensation.

B. Meat Processing

The processes of slaughtering and processing are not, by their nature, extremely precise ones. Infectious material from the most infectious parts of the cow, the brain and spinal cord, may spread to other parts of the animal. Pneumatic stunning devices, which stun the animal prior to slaughter by injecting a bolt and compressed air into the head, have been shown to spread potentially infectious brain tissue to other parts of the body. Although the industry appears to be reducing its use of pneumatic stunning devices, this should be given the force of federal regulation and banned. These devices are now banned for use in cattle in Europe.

European countries require that the brain and spinal cord be removed early in the slaughtering process. However, in the United States, processes vary widely and are not effectively regulated. We therefore support a regulation that would require the removal of the brain and spinal cord before further processing, since these organs contain the highest levels of infectious material.

Two other meat processing methods have also come under scrutiny. In one, mechanically separated product (MSP), bones with attached muscle are crushed and pushed through an extruder to create a paste. Bone fragments are removed by a sieve-like mechanism. Both spinal cord and dorsal root ganglia (nerve tissue next to the vertebrae), which have demonstrable BSE infectivity, can enter MSP. In the other processing method, advanced meat recovery (AMR), muscle fragments are also removed from bone; this material can become part of ground beef. Early AMR machines used a belt to shave meat off bones, but later AMR machines use a "bone press" that differs from MSP only in degree. While MSP inherently involves the crushing of bones and is thus more likely to introduce nerve tissue into the product than AMR, 1997 USDA inspection records obtained by the Government Accountability Project through the Freedom of Information Act clearly demonstrate that spinal cord can be part of the material generated by AMR. Four of 34 AMR samples sent by USDA inspectors to a USDA laboratory because they were suspected of containing spinal cord tissue turned out to actually contain central nervous system tissue. It is possible that AMR machines could be redesigned to minimize the probability of crushing bones and thus including spinal cord. The USDA began such a rulemaking procedure three years ago, but the rule has still not been finalized. To prevent vCJD, we

therefore support a ban on the production of MSP from vertebrae and the issuance of a final rule for better-designed AMR processes that would prevent the inclusion of spinal cord.

Is the U.S. doing enough testing to detect the disease?

To date, the U.S. surveillance efforts for BSE have been quite inadequate. Only 11,954 cow brains had been examined by the USDA in the ten-year span ending in 2000. (Some 40 million cattle are slaughtered annually in the U.S.) By comparison, France, a country which, importantly, has a proven BSE epidemic, is now testing about 20,000 brains per week.

Under current USDA procedures, all cows with neurological symptoms are supposed to be tested for BSE and, regardless of the result, excluded from the food chain. Cows that are unable to ambulate, so-called downer cows, are only occasionally tested. The USDA did not begin testing downer cows until 1993 but has now increased such testing to about 1,900 in 2000 (http://www.aphis.usda.gov/oa/bse/bsesurvey.html). This represents about 1% of all downer cows brought to slaughter in the U.S. The USDA has promised to increase such testing to 5,000 per year in 2001, a move we fully support. Testing of healthy cows does not seem justified in the U.S. at present as the prevalence of disease would almost certainly be lower than in downer cows or those with neurological symptoms. Moreover, even in countries with clear BSE epidemics, BSE-positive normal animals have only been detected extremely rarely if ever, even as the disease is detected in downer cows and those with neurological symptoms.

Testing for the presence of BSE in cow brain can be very time-consuming. However, while three rapid tests for BSE are on the market in Europe, none are on the market in the U.S. It is imperative that these tests be evaluated by the FDA and that test performance characteristics be made public.

Surveillance for human CJD and vCJD is coordinated through the Centers for Disease Control and the National Prion Disease Pathology Surveillance Center at Case Western Reserve University. The Center has examined the brains of about 300 patients with CJD in the past four years. This represents an estimated 39% of patients with CJD in 2000, whereas in Germany and Britain the brains of almost all patients with CJD are examined by pathologists. Canada has recently revamped its surveillance system and provides much more funding for such efforts than does the U.S.

The U.S. government also needs to do more to increase the overall hospital autopsy rate in this country, which has declined from over 40% after World War II to under 10% at present, as well as to increase the rate of examination of brain material specifically. Currently, hospitals and families bear the costs of autopsies, including transportation costs; they should be reimbursed for these costs. The government should also consider creating a network of regional pathology centers to do brain examinations for CJD and needs to do more to contact all neurologists to inform them of the current surveillance system.

Are there medical practices that might transmit BSE and vCJD?

In weighing whether products that are transfused or transplanted into humans should be restricted, the essential questions are: 1. What is the probability of transmission of infection?; 2. Are their suitable alternatives to the material?; and 3. Would the restriction of the material produce a shortage of a vital medical product?

While there has never been a documented case of CJD or vCJD transmitted by blood transfusion, the agent is present in white blood cells (inevitably present to some extent in even red blood cell transfusions) and, in an experiment, a sheep was recently infected by transfusion from a cow with BSE. In 1999, the FDA's TSE Advisory Committee recommended a ban on blood donations from potential donors who had spent more than a total of six months in Britain between 1980 and 1996. The Committee determined that the impact on the blood supply would be manageable and data collected since the restriction on British donors confirm that the supply of blood remained stable after the ban was enacted. In January 2001, with cases of vCJD in France and of BSE in Europe mounting, the Committee extended this recommendation to include France, Portugal and Ireland, although with a 10-year cumulative residency requirement, since BSE and vCJD case rates are lower in those countries than in Britain. The FDA should adopt the Committee's recommendation.

Similar travel restrictions should be placed on cadaveric cornea donors, especially because as many as three cases of CJD due to corneal transplantation have been documented. Due to the existing shortages of other transplantable organs such as heart and bone marrow, and the failure to document CJD transmission associated with their transplantation, a travel restriction on such organ donors is not justified. On the other hand, because the U.S. is a net exporter of cornea, we are not concerned that there would be a shortage of cornea were a travel restriction to be implemented.

Finally, there is the issue of vaccines. In 1993, the FDA wrote to the manufacturers of FDA-regulated products and in a voluntary Guidance instructed manufacturers to no longer source materials for their products from BSE-affected countries. It repeated the admonition in 1996. Nonetheless, at least six manufacturers simply ignored the Guidance, which does not have the force of a regulation, and continued to source bovine materials for the production of vaccines from BSE-affected countries. The FDA only learnt that its recommendation had been disregarded in early 2000. By then, millions of doses of vaccines such as polio and diphtheria, tetanus, and pertussis (DTP) were injected into Americans, including small children. At a TSE Advisory Committee meeting in July 2000, Committee members agreed that the risk of disease transmission through these vaccines is extremely small and that there is no evidence that vCJD has been spread through this route. Nonetheless, this event was a reminder of the dangers presented by agencies that fail to regulate and industries that act in arrogant disregard of the government.

The lesson of the vaccine debacle applies more broadly to our efforts to reduce the risks of BSE and vCJD: for the public to be adequately protected, government will have to take forceful action -- regulations, not guidelines -- and not simply depend upon voluntary actions by industry.

Summary of actions necessary to reduce the risk of BSE and vCJD in the U.S.

- Increase inspection capacity at the borders

- Repeal the Dietary Supplement Health and Education Act

- As an alternative to repeal, pass legislation that would require mandatory adverse event reporting for all dietary supplement manufacturers, mandatory risk warnings, company and product registration, and identification of the raw ingredients and the source (by country) for each of the ingredients

- Release Good Manufacturing Practice regulations for dietary supplements

- Enforce compliance with the mammal-to-ruminant feeding ban

- Remove the plate waste exemption from the feeding ban

- Assure that CWD-affected deer and elk herds do not enter the food chain

- Provide compensation for ranchers with CWD-affected deer and elk herds

- Ban pneumatic stunning devices

- Remove brain and spinal cord from slaughtered cows before further processing

- Ban mechanically separated product produced from vertebrae

- Issue regulations on advanced meat recovery to preclude the introduction of spinal cord

- Continue to expand testing of downer cows

- Expand the current CJD and vCJD surveillance system and notify neurologists of its existence

- Adopt the FDA's TSE Advisory Committee's recommendation restricting blood donations from those with extensive histories of residence in France, Portugal and Ireland

- Create travel restrictions for cornea donors similar to those for blood donors

- Promulgate regulations preventing the sourcing of materials for the production of vaccines from BSE-affected countries